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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,233	12/12/2001	Yuriy M. Dunayevskiy	HKI-107AX	8808
207	7590	05/06/2004	EXAMINER	
WEINGARTEN, SCHURGIN, GAGNEBIN & LEBOVICI LLP TEN POST OFFICE SQUARE BOSTON, MA 02109			DIAMOND, ALAN D	
			ART UNIT	PAPER NUMBER
			1753	
DATE MAILED: 05/06/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,233

Applicant(s)

DUNAYEVSKIY ET AL.

Examiner

Alan Diamond

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>03182002</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Objections

2. Claim 12 is objected to because of the following informalities: In claim 12, at line 4, the term "s⁻¹" should be changed to "(s⁻¹)". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The line numbers referred to below are claim line numbers, not page line numbers.

Claim 1 is indefinite because the term "the target/sample mixture" at line 15 and bridging lines 20 and 21 lacks positive antecedent support in claim 1 itself. The same applies to dependent claims 2-33. In particular, said term also appears in claim 3 at line 2 and in claim 5 bridging lines 2 and 3.

Claim 2 is indefinite because "the reference standard" bridging lines 1 and 2 lacks positive antecedent support in claim 1.

Claim 7 is indefinite because it is not clear which "migration pattern" is being referred to when claim 7 depends from claim 2. Note that claim 2 refers to a migration

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pattern for the reference standard, and that claim 1 from which claim 2 depends refers to a migration pattern in step (d).

In claim 9, at the last line, the term "thereof" should be changed to "the sewage" so as to particularly point out what is being referred to.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-11 and 16-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al, EP 848251 A2.

Liu et al teaches an electrophoresis method for determining an analyte in a sample (comparable to screening a complex material for a candidate ligand) comprising the steps of introducing a labeled first reagent (comparable to detectable, competitive ligand), a sample comprising the analyte (comparable to candidate ligand) and a further reagent (comparable to pre-selected target) into an electrophoresis capillary, mixing the compounds "on-column" because of their different migration speeds and detecting bound and/or unbound labeled first reagent (see column 7, line 32 to column 8, line 29). The running buffer has a pH of 6 to 10, and a salt concentration of about 20 to about 500 mM (see col. 9, lines 23-35). The temperature of the column is 10 to 50°C (see col. 9, lines 1-7). The capillary has a length of 10 to 100 cm (see col. 8, lines 41-58). Liu et

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al teaches the limitations of the instant claims other than the difference which is discussed below.

The main difference between the method of Liu et al and that defined in instant claim 1 is the fact that according to the instant method, target and candidate ligand are mixed together before injection into the capillary. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have mixed Liu et al's analyte (containing candidate ligand) and the further reagent (containing the pre-selected target) before injection into the capillary so that when analyte/first reagent mixture has been injected into the column, it can be mixed with the labeled first reagent.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,299,747, US 2002/0052006, US 6,432,651, and US 6,524,866 are hereby made of record.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alan Diamond whose telephone number is 571-272-1338. The examiner can normally be reached on Monday through Friday, 5:30 a.m. to 2:00 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Alan Diamond
Primary Examiner
Art Unit 1753

A handwritten signature in black ink, appearing to read 'Alan Diamond', with a stylized flourish at the end.

Alan Diamond
May 4, 2004